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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,342	10/23/2001	Michael Sogard	NIKOP027/PA0427	7706

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BEYER WEAVER & THOMAS LLP
P.O. BOX 778
BERKELEY, CA 94704-0778

EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/038,342

Applicant(s)
Sogard

Examiner
Maurie G. Baker, Ph.D.

Art Unit
1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

DETAILED ACTION***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-14, drawn to a method for performing a hybridization assay, classified variously, for example, in class 435, subclass 6 OR class 436, subclass 147.
 - II. Claims 15 and 16, drawn to a method for performing a binding assay, classified variously, for example, in class 436, subclass 501 OR class 436, subclass 147.
 - III. Claims 17-20, drawn to an apparatus for performing a hybridization assay, classified variously, for example, in class 435, subclass 286.1 OR class 422, subclass 82.12.
 - IV. Claims 21-32, drawn to a method, classified variously, for example, in class 435, subclass 6 OR class 436, subclass 147.
 - V. Claims 33-37, drawn to an apparatus, classified variously, for example, in class 435, subclass 286.1 OR class 422, subclass 82.12.
2. The inventions are distinct, each from the other because of the following reasons:
3. Groups I, II and IV are different methods. The methods are different because they use different steps, reagents and/or will produce different results/products. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the methods of Groups I & II differs from the method of Group IV because they use completely different steps, completely different reagents and have completely different end results. The method of Group IV requires a container with a solution of DNA and

the creation of thermal gradients, which results in the redistribution of DNA. This is completely different from the methods of performing a hybridization assay (Group I) or performing a binding assay (Group II). For the methods of Groups I and II, these are different from each other as Group I is a method for performing a hybridization assay and Group II is a method for performing a binding assay. Group I requires an oligonucleotide array and a hybridization mixture not required by Group II.

4. Groups III and V are different apparatuses. The apparatuses are different because they use different components and have different functions. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the apparatus of Group V requires both (1) a container having a solution of DNA and (2) a system that results in the redistribution of DNA that are not required by the apparatus of Group III.

5. Groups I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by hand; that is, the process of Group I could be practiced by manually heating various sections of the array without the use of "temperature control blocks".

6. Groups IV and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used to practice another and materially different process such as redistribution of DNA in the process of making an array.

7. Group II is not related to either of Groups III or V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, neither of the apparatuses of Groups III or V are apparatuses for practicing a method for performing a binding assay.

8. Therefore, the groups that describe these inventions each have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group could support a separate patent.

9. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. Please note that even though some of these groups

could be classified in the same class and/or subclass, this has no effect on the non-patent literature search. The different inventions would require completely different searches in these databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Election of Species

10. This application contains claims directed to patentably distinct species of the claimed invention for **Groups I, II and IV**. Election is required as follows.

11. If applicant elects the invention of **Group I**, applicant is required to elect from the following patentably distinct species. Claims 1 and 5-7 are generic. Election is required as set forth below. One species from each of A and B below should be elected.

A. Species of thermophoretic conditions

A *specific* species of "thermophoretic conditions" should be elected, for purposes of search. Both the type of thermophoretic conditions and the result/orientation thereof should be delineated.

B. Species of detectable label

A *specific* species of detectable label should be elected, for purposes of search.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

12. If applicant elects the invention of **Group II**, applicant is required to elect from the following patentably distinct species. Claim 15 is generic. Election is required as set forth below. One species from each of A, B and C below should be elected.

A. Species of target and array

A *specific* species of target and array used in the claimed method should be elected, for purposes of search. Both the type of target and the type of array should be elected.

B. Species of thermophoretic conditions

A *specific* species of "thermophoretic conditions" should be elected, for purposes of search. Both the type of thermophoretic conditions and the result/orientation thereof should be delineated.

C. Species of detectable label

A *specific* species of detectable label should be elected, for purposes of search.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

13. If applicant elects the invention of **Group IV**, applicant is required to elect from the following patentably distinct species. Claims 21-26 and 30-32 are generic. Election is required as set forth below.

Species of detectable label

A *specific* species of detectable label should be elected, for purposes of search.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

14. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

15. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and *a listing of all claims readable thereon*, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

16. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

17. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

18. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


20. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

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22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
September 17, 2003



MAURIE GARCIA BAKER PH.D
PRIMARY EXAMINER